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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,949	06/07/2006	Magne Solbakken	PN0302	6745

36335 7590 10/27/2008
GE HEALTHCARE, INC.
IP DEPARTMENT
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EXAMINER	
SCHLIENTZ, LEAH H	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
10/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,949	SOLBAKKEN ET AL.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,7 and 9-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,7 and 9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Receipt

Applicant's Response, filed 10/6/08, in reply to the Office Action mailed 8/8/08, is acknowledged and has been entered. Claims 1, 4, 7 and 9-11 are readable upon the elected invention and are examined herein on the merits for patentability.

Response to Arguments

Applicant's arguments, see pages 2-6 of the Response, with respect to the rejection of claims 1, 4, 7 and 9-11 under 35 U.S.C. 103(a) as being unpatentable over Klaveness in view of Cuthbertson have been fully considered and are persuasive. Therefore the rejection has been withdrawn, as the Cuthbertson reference has been disqualified as prior art to the instant application. However, upon further consideration, a new ground(s) of rejection is made in view of newly discovered prior art references.

New Grounds for Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

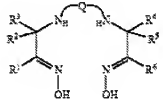
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 7 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klaveness *et al.* (US 6,264,914) in view of Forster *et al.* (WO 02/053192, whereby US 7,052,672 is relied upon as equivalent).

Klaveness discloses compositions of the formula V-L-R, where V is an organic group having binding affinity for an angiotensin II receptor site, L is a linker moiety, and R is a moiety detectable in *in vivo* imaging of a human or animal body (abstract). The composition may be used to image cardiovascular diseases and disorders. Losartan is a preferred vector (column 2, line 67; column 3, line 17). Most commonly, the linker comprises two or more reactive moieties connected by a spacer element (column 13, lines 18 – 20). The spacer may be include polyamino acids, homo- and co-polymers of lysine, glutamic acid and aspartic acid, and polypeptides (column 14, lines 21 – 23). See also column 19, lines 39 – 45. The reporter groups include metal radionuclides, such as ^{90}Y, ^{99m}Tc, etc. chelated by chelant groups on the linker moiety (column 23, line 55 – column 25). An exemplified compound is a Tc chelate of N-(N-MAG-3-glycyl)-Losartan (claim 3, compound v). A variety of chelating moieties may be used to chelate a radionuclide as the reporter moiety, R (see column 24 – 25).

Klaveness teaches that a variety of chelating agents are suitable to bind the radionuclude, but does not specifically teach that the chelating agent is a pentleneamine oxime.

Forster teaches chelating agents for ^{99m}Tc for use as radiopharmaceuticals, including diaminedioximes of the formula shown below:



Most preferred diaminedioximes are propyleneamine oxime, butyleneamine oxime or pentyleneamine oxime. One or more of the R groups may be conjugated to a biological targeting group (see column 4, line 48—column 5, line 15).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute a diaminedioxime chelator such as pentyleneamine oxime taught by Forster for the chelating agent employed in the V-L-R compounds taught by Klaveness. Klaveness teaches that a variety of chelating agents may be employed to bind a radionuclide. One would have been motivated to do so, and would have had a reasonable expectation of success in doing so, because the diaminedioxime chelators are taught in the prior art to be functional equivalents for use in binding radionuclides, as shown by Forster. The Supreme Court in KSR International Co. v. Teleflex Inc., 550 U.S. ___, 82 USPQ2d 1385, 1395-97 (2007) identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach"

to the determination of obviousness as laid down in Graham. One such rationale includes the simple substitution of one known element for another to obtain predictable results. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. See MPEP 2143. In the instant case, the substituted components (chelating agents for radionuclides) and their functions were known in the art at the time of the instant invention. One of ordinary skill in the art could have substituted one known chelating agent for another, and the results of the substitution would have been predictable, that is chelation of a radionuclide via a V-L-R compound for targeted radioimaging.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 7 and 9-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 4 of U.S. Patent No. 6,264,914, in view of Forster (US 7,052,672). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to compositions of formula V-L-R wherein V is an organic group having binding affinity for an angiotensin II receptor, L is a linker moiety, and R is a reporter moiety. The reporter moiety includes radionuclides conjugated to a chelating ligand; the linkers include amino acids; and the compounds are used for methods of imaging a human or animal subject. While '914 does not specifically claim pentaleneamine oxime as the chelator, it would have been obvious to one of ordinary skill in the art to use such a chelator when '914 is taken in view of Forster. One would have been motivated to do so, and would have had a reasonable expectation of success in doing so, because the diaminedioxime chelators are taught by Forster to be functional equivalents for use in binding radionuclides, such as ^{99m}Tc for use in radiopharmaceuticals (column 14-15). Accordingly the claims are overlapping in scope and are obvious variants of one another.

Claims 1, 7 and 9-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 10 of U.S. Patent No. 6,921,525, in view of Forster (US 7,052,672). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to compositions of formula V-L-R wherein V is an organic group having

binding affinity for an angiotensin II receptor, L is a linker moiety, and R is a reporter moiety. The reporter moiety includes radionuclides conjugated to a chelating ligand; the linkers include amino acids; and the compounds are used for methods of imaging a human or animal subject. While '525 does not specifically claim pentaleneamine oxime as the chelator, it would have been obvious to one of ordinary skill in the art to use such a chelator when '525 is taken in view of Forster. One would have been motivated to do so, and would have had a reasonable expectation of success in doing so, because the diaminedioxime chelators are taught by Forster to be functional equivalents for use in binding radionuclides, such as ^{99m}Tc for use in radiopharmaceuticals (column 14-15). Accordingly the claims are overlapping in scope and are obvious variants of one another.

Claims 1, 7 and 9-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 5 of U.S. Patent No. 7,182,934, in view of Forster (US 7,052,672). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to compositions of formula V-L-R wherein V is an organic group having binding affinity for an angiotensin II receptor, L is a linker moiety, and R is a reporter moiety. The reporter moiety includes radionuclides conjugated to a chelating ligand; the linkers include amino acids; and the compounds are used for methods of imaging a human or animal subject. While '934 does not specifically claim pentaleneamine oxime as the chelator, it would have been obvious to one of ordinary skill in the art to use such

a chelator when '934 is taken in view of Forster. One would have been motivated to do so, and would have had a reasonable expectation of success in doing so, because the diaminedioxime chelators are taught by Forster to be functional equivalents for use in binding radionuclides, such as ^{99m}Tc for use in radiopharmaceuticals (column 14-15). Accordingly the claims are overlapping in scope and are obvious variants of one another.

Claims 1, 4, 7 and 9-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. 7,431,914. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to compositions of formula V-L-R, or V-L-Z, wherein V is a vector having binding affinity for an angiotensin II receptor, L is a linker moiety, and R is a reporter moiety, as in the instant case, or Z is a chelating agent carrying an imaging moiety, as in the '914 patent. Both sets of claims teach the same chelators, the imaging moiety may be a radionuclide, and the compounds are used for methods of generating images of a human or animal body. Accordingly the claims are overlapping in scope and are obvious variants of one another.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

LHS